Remarks

In view of the above amendments and the following remarks, reconsideration and further examination are respectfully requested.

In the previous response, claims 1-9 were canceled for consideration in a potential divisional application. Claim 10 has been amended in the present response. This amendment to claim 10 is supported by the application as originally filed. For example, support can be found at page 11, lines 15-30 of the specification and in FIGS. 2-4 of the drawings as well as elsewhere throughout the application. Claims 31 and 32 have been added, and it is believed that these claims are supported by the application as originally filed. For instance, support for claims 31-32 can be found at pages 9-11 of the specification and FIGS. 1-6 of the drawings as wells as elsewhere throughout the application. As a result of these amendments, claims 10-32 are currently pending.

The application was subject to a restriction requirement, and Group II was elected in a prior response. As a result, claims 14-16, 26 and 30 were previously withdrawn from consideration. In the present response claims 31 and 32 were added, and it is believed that claims 31 and 32 read on Group II. Consequently, claims 10-13, 17-25, ,27-29, 31, and 32 are currently pending and under consideration.

Objections to the Specification

In item 5 of the Office Action, the specification was objected to for informalities. The specification has been amended to corrected the cited informalities.

Claim Objection

In item 6 of the Office Action, claim 22 was objected to for informalities. The cited informality has been corrected in the present response, and it is therefore requested that the objection be withdrawn.

Claim Rejections under 35 USC §102

Claim 10

In item 8 of the Office Action, independent claim 10 was "rejected under 35 USC 102(e) as being anticipated by Uchigaki et al (US Pat No. 6849052)." Independent claim 10 has been amended to clarify that when the sample end is at the second position, the sample end is located farther away from the incision than at the first position.

It is believed that claim 10, as currently amended, is not anticipated by Uchigaki et al. For example, Uchigaki et al. fails to disclose or suggest "a sampling end disposed proximal to the lancet that is moveable between a first position over the incision and a second position where the sample end is located farther away from the incision than at the first position" and "a deflection mechanism engageable with the sampling mechanism to deflect the sampling end of the sampling mechanism from the first position to the second position in order to allow the lancet to form the incision" as recited in claim 10. It should be recognized that Uchigaki et al. does not have such a deflection mechanism. Rather than having the ability to move to the end of the biosensor 36 farther away from the incision, the motor 41 along with the eccentric cam 42 in Uchigaki et al. only has the ability to push or slide the biosensor 36 closer towards the incision. As described at column 8, lines 44-48 of Uchigaki et al., "the eccentric cam 42 is driven to advance the biosensor 36 (S06). Thus, as shown in FIGS. 4 and 11, the biosensor 36 is moved so that the inlet of the body fluid path 36b projects into the drawn blood" (emphasis added). By its very nature, the eccentric cam 42 has no ability to retract the biosensor 36 to a position that is farther away from the incision so as to prevent interference with the lancet 31 during lancing.

As another example, Uchigaki et al. fails to disclose or suggest "wherein at least a portion of the sampling mechanism is resilient in order to return to the first position after the incision is formed" as recited in claim 10. In the Office Action, it was recognized that Uchigaki et al. does not expressly disclose such a feature, but it was nevertheless alleged on page 4 that "at least a portion of the sampling mechanism is inherently resilient because said sampling mechanism is movable from a first position to a second position, thus said sampling mechanism can also return to the first position after the incision is formed." For an element to be inherently disclosed, it must "necessarily be present in the thing described in the reference." In re Robertson, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Indeed, inherency "may not be established by

probabilities or possibilities . . .The mere fact that a certain thing may result from a given set of circumstances is not sufficient." 49 USPQ2d at 1951. Contrary to the above-mentioned allegation made in the Office Action, it is not a necessary consequence that the biosensor 36 in Uchigaki et al. is resilient. Rather, it is conceivable, and very likely in fact, that the biosensor 36 is not resilient. Specifically, the biosensor 36 is stationary until the eccentric cam arm 42 pushes the biosensor 36 forward, in a single-step or two-step progression, to an advanced position where it collects blood (see, column 9, lines 58-67). Once at the advanced position, the biosensor 36 remains there and does not spring back to the retreated position. Given that the biosensor 36 is not necessarily resilient, it is then not inherently disclosed by Uchigaki et al.

For these and other reasons, it is believed that claim 10 and its dependent claims are allowable over the references of record.

Claim 24

In item 8, independent claim 24 was "rejected under 35 USC 102(e) as being anticipated by Uchigaki et al (US Pat No. 6849052)." Uchigaki et al., however, fails to anticipate claim 24 because it fails to disclose all of the features recited in claim 24. In a first example, Uchigaki et al. fails to disclose or suggest "a test strip that is biased over the incision site" as recited in claim 24. The biosensor 36 in Uchigaki et al. in actuality is not biased over the incision site, but instead, the biosensor 36 is normally positioned at a retreated position that is located away from the incision site.

As a second example, Uchigaki et al. fails to disclose or suggest "means for deflecting the test strip from the incision site." As should appreciated, this feature utilizes means plus function language in accordance with 35 U.S.C. §112, paragraph 6. Uchigaki et al. fails to anticipate claim 24 because Uchigaki et al. fails to disclose a structure that performs the identical function of this recited feature. Specifically, the eccentric cam 42 of Uchigaki et al. does <u>not</u> deflect the biosensor 36 from the incision site, but rather, the eccentric cam 42 pushes the biosensor 36 <u>towards</u> the incision site, which is contrary to the recited function.

For these and other reasons, claim 24 and its dependent claims are allowable over the references of record.

Claim 27

In item 8, independent claim 27 was "rejected under 35 USC 102(e) as being anticipated by Uchigaki et al (US Pat No. 6849052)." Uchigaki et al., however, fails to anticipate claim 27 because it fails to disclose all of the features recited in claim 27. For instance, Uchigaki et al. fails to disclose or suggest "a deflection mechanism configured to deflect the means for collecting the body fluid from the incision to allow the means for forming the incision access to the incision site during formation of the incision." It should be appreciated that the eccentric cam 42 in Uchigaki et al. does not correspond to the recited deflection mechanism. Instead of deflecting the biosensor 36 from the incision, the eccentric cam 42 in Uchigaki et al. pushes the biosensor 36 towards the incision. For these and other reasons, claim 27 and its dependent claims are allowable over the references of record.

New Claims

Claim 31

It is believed that new independent claim 31 is allowable over the references of record. For example, Uchigaki et al. fails to disclose or suggest "a cam arm coupled to the lancet to move in unison with the lancet as the lancet travels to cut the incision, the cam arm being positioned to bend the test strip from the position where the lancet cuts the incision" as recited in claim 31. The eccentric cam 42 in Uchigaki et al. is not configured to bend the biosensor 36 out of the way when the lancet 31 cuts the incision, but rather, the eccentric cam 42 pushes the biosensor 36 so that it slides towards the incision to collect fluid bleeding from the incision. Moreover, it should be recognized that Uchigaki et al. does not have "the test strip being configured to spring back over the incision to collect body fluid once the lancet retracts from the incision" as recited in claim 31. Instead of bending and springing back, the biosensor 36 remains flat or rigid throughout the fluid collection process. For these and other reasons, it is submitted that claim 31 and its dependent claim is allowable over the references of record.

Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is earnestly solicited. If after reviewing this amendment the Examiner feels that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the undersigned representative by telephone to resolve such issues.

Respectfully submitted,

By /Charles P. Schmal #45,082/

Charles P. Schmal, Reg. No. 45082
Woodard, Emhardt, Moriarty, McNett & Henry LLP
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456